K010554

MAY 2 5 2001

510(k) Summary
Bionx Implants Inc.
Meniscus Arrow™ Sheath

Submitter's Name, Address, Telephone Number, and Contact Person

Bionx Implants, Inc.
1777 Sentry Parkway West
Gwynedd Hall, Suite 400
Bluebell, PA 19422

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President and Chief Executive Officer
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Bionx Implants Ltd.
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Regulatory Affairs Assistant
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Finland
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Facsimile: 358-3-316 5629

Date prepared: February 19th, 2001

Name of the device:

A.	Trade or Proprietary Name:	Meniscus Arrow™
B.	Common Name:	Bioabsorbable Meniscus Arrow System
C.	Classification Name:	Biodegradable Orthopedic Soft Tissue Fixation Device (MAI)

A.	Trade or Proprietary Name:	Meniscus Arrow Sheath
B.	Common Name:	Disposable, sterile, single use orthopedic manual surgical instrument
C.	Classification Name:	Orthopedic manual surgical instrument, product code LXH, C.F.R. Section 888.4540

Predicate Devices:

Biofix®	Biodegradable Meniscus Arrow System, Bionx Implants Inc. (Previous Bioscience Inc.), cleared 3/4/1996
K993453	Meniscus Arrow System, Bionx Implants Inc., cleared 10/9 1999

Intended Use:

The predicate devices are Bionx Implants Inc. Biofix® Biodegradable Meniscus Arrow System (K955768, K993453) with their current instrument sets. This amendment of new, disposable, sterile part into those instrument sets has no effect on the approved indications and this new part can not be used as individual, separate instruments but just as a part of instrument sets.

The Meniscus Arrow™ Sheath is designed to aid in the insertion of the Meniscus Arrow cannulas when establishing access to the joint space. The sheath will aid in the prevention of soft tissue damage during cannula insertion.

This part is in very limited contact with the body and it does not effect on the original indications.

Device Description:

Shaft of the sheath, which is the only part, which is inserted into body, is made of gamma stabile medical grade polyamide polymer. This very same raw material is used also in more demanding medical devices like in cardiovascular catheters.

Substantial Equivalence:

Meniscus Arrow™ with the instrument sets supplemented with sheaths:

- has the same indicated use
- uses the same operating principle
- is packaged and sterilized using the same materials and processes
- has the same shelf life 3 years
- has the same trade name

The purpose of these sheaths is aiding the prevention of soft tissue damage during installation of implants. No turning, bending or shear forces are conducted on them. This amendment is not causing any changes to original indications of the predicate device or any design changes to Meniscus Arrow implant. The parts of instrument set can not be used as separate, individual instruments for other purposes. We conclude this amendment of disposable, sterile part into instrument sets does not raise any problems concerning safety or efficacy of the implant devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2001

Ms. Tuija Annaza
Quality Manager
Bionx Implants, Inc.
1777 Sentry Parkway West
Gwynedd Hall, Suite 400
Bluebell, Pennsylvania 19422

Re: K010554
Trade/Device Name: Meniscus Arrow Sheath
Regulation Number: 888.3040
Regulatory Class: II
Product Code: HWC and MAI
Dated: February 23, 2001
Received: February 26, 2001

Dear Ms. Annaza:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K010554

Device Name: Meniscus Arrow™

Indications for Use:

The Meniscus Arrow™ is intended for arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle) located in the vascular area of the meniscus (e.g. "red-red" and "red-white" zones) in conjunction with immobilization during healing.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010554